EXHIBIT 4

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA Ex Rel VEN-A-CARE OF THE FLORIDA KEYS, INC. a Florida Corporation, by and through its principal officers and directors, ZACHARY T. BENTLEY and T. MARK JONES, Plaintiff,	
v.	**CIVIL ACTION NO. 00 CV10698 MEL**
[redacted]	**FILED IN CAMERA AND UNDER SEAL**
	SECOND AMENDED COMPLAINT
DEY, INC.; [redacted] Defendants.	**For Money Damages and Civil Penalties Under the False Claims Act 31 U.S.C. §§3729-3732**

SECOND AMENDED COMPLAINT
FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE FALSE CLAIMS ACT 31 U.S.C. §§3729-3732

CIVIL ACTION NO. 00 CV 10698 MEL

COMES NOW, the UNITED STATES OF AMERICA ("UNITED STATES" or "GOVERNMENT"), by and through VEN-A-CARE OF THE FLORIDA KEYS, INC. ("VEN-A-CARE" or "the Relator"), and its principal officers and directors, ZACHARY T. BENTLEY and T. MARK JONES, and by and through the undersigned attorneys on behalf of the UNITED STATES and on the Relator's own behalf and brings this action against [redacted] DEY INC.; [redacted] (sometimes referred to collectively as "DEFENDANTS"), for money damages and civil penalties arising out of the DEFENDANTS' violations of the Federal False Claims Act, 31 U.S.C., §§3729-3732 from on or about April 7, 1994, to the present date.

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[redacted]

SECTION NO. 1
SUMMARY OF THE ACTION

1. This is an action for damages, treble damages, civil penalties and costs against the DEFENDANTS for violation of the False Claims Act as set out in Counts I through VII, pages 174 through 189.

2. The Medicare and Medicaid programs pay claims for the prescription drugs specified herein only if three distinct requirements are met. First, the drug manufacturer must make price and cost information about the drug publicly available. Second, the programs must elect to cover the drug when medically necessary. Third, the physician, pharmacy or other health care provider who purchases the drug must confirm that it was administered or dispensed to an eligible person covered by the applicable program. In some cases, most notably that of the Texas Medicaid Program, manufacturers must report costs and prices directly to the program to satisfy the price disclosure requirement.

3. The DEFENDANTS benefitted economically when health care providers purchased their drugs in anticipation of Medicare or Medicaid reimbursement, and each of the DEFENDANTS has knowingly made cost and price information about its drugs publicly available, at least in part, to satisfy the first requirement for reimbursement by Medicare and Medicaid. In the case of the specified prescription drugs at issue, the DEFENDANTS knowingly reported inflated cost and price information that caused Medicare and Medicaid to pay excessive reimbursements.

4. This false claims action reveals an intentional scheme by certain pharmaceutical companies, (the " DEFENDANTS"), to arrange financial inducements aimed at pharmacies, specialized physicians [redacted] and clinics to increase sales of their prescription drugs which are reimbursed by the Medicare and States' Medicaid programs. The financial inducements arranged by the DEFENDANTS are intentionally concealed so that federally funded health care programs will not benefit from the true prices in the marketplace. The DEFENDANTS, participating in what has amounted to a kickback scheme, created financial inducements by falsely inflating reports of the price and cost of their drugs and through additional inducements such as free goods, direct monetary payments and rebates thus causing the Medicare and States' Medicaid programs to pay inflated reimbursement to the pharmacy, specialized physician or clinic providing the covered drug to the drug recipient (collectively "the Providers"). Each of the participating DEFENDANTS made a decision to report average wholesale prices, direct prices, and/or other prices or costs that they knew would be used by Medicare and Medicaid in establishing reimbursement amounts. Each DEFENDANT, had it so chosen, could have reported prices and costs for the specified drugs that were consistent with the prices actually being charged and paid in the marketplace. The DEFENDANTS were free to elect not to report prices and thus not have their drugs covered by Medicare and Medicaid. Rather than choose either of these paths, each of the participating DEFENDANTS opted to report inflated prices and costs for the express purpose of

creating a "spread" between the resulting Medicare and Medicaid reimbursement amounts and the prices actually being charged to the Providers. The DEFENDANTS were fully aware that the Medicare and Medicaid programs were required by their reimbursement policies to use the DEFENDANTS' reported drug prices and costs in calculating reimbursement amounts. The following chart demonstrates how DEFENDANTS DEY and [redacted] caused the Medicare program to pay materially inflated reimbursement amounts for the respiratory drug Ipratropium Bromide 0.02% Sol., by reporting inflated prices for the drug for reimbursement purposes while actually selling the drug for a substantially lower amount. The second column in the chart represents the amount by which the Providers were reimbursed by Medicare for the drug pursuant to the prices Dey and [redacted] reported. The third column represents VEN-A-CARE's true prices paid for Dey and [redacted] Ipratropium Bromide. The chart shows that unlike the Providers, the Medicare program never benefitted from the Dey and [redacted] price reductions which actually did take place with respect to the drug.

Ipratropium Bromide 0.02% Sol.
HCPCS code J7645 & (K0518)

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	VenACare COST PER MEDICARE UNIT	"SPREAD" (PROFIT) $	"SPREAD" (PROFIT) %	MEDICARE EXPENDITURES $
1995	$ 3.11/mg. ($0.62/ml)	$3.11	$0.00	0%	$14,426,108
1996	$ 3.75/mg. ($0.75/ml)	$3.26	$0.49	15%	$47,388,622
1997	$ 3.50/mg. ($0.70/ml)	$2.15	$1.35	63%	$96,204,639
1998	$ 3.34/mg.	$1.70	$1.64	96%	$176,887,868
1999	$ 3.34/mg.	$1.60	$1.74	108%	$253,400,414
2000	$ 3.34/mg.	$0.94	$2.40	255%	$347,527,960
2001	$ 3.34/mg.	$0.82	$2.52	307%	

* Medicare Units were converted from ml's to mg's for the years 1995,1996 &1997 (5 ml=1 milligram) & 1998-2001 @ 95% of AWP

5. [redacted]

A. DRUG MANUFACTURERS' FALSE PRICE REPRESENTATIONS INVOLVING RETAIL PHARMACIES

6. The DEFENDANTS falsely represented the prices that they charged wholesalers and direct prices for certain of their generic prescription drugs (hereinafter sometimes referred to as the "specified retail pharmacy drugs") in order to cause various State Medicaid programs to pay claims in excessive amounts. More than half of the amounts paid consisted of federal funds from which the States were required to

pay claims based upon the drug's Estimated Acquisition Cost ("EAC") to the pharmacy submitting the claim. 42 CFR § 447.331. The DEFENDANTS knew that each of the States' Medicaid programs had implemented a mechanism to estimate the acquisition cost of prescription drugs to a pharmacy. Most states used the DEFENDANTS' representation of their Average Wholesale Price ("AWP") (hereinafter sometimes referred to as "AWP STATES") and some States including but not limited to Alabama, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island, and Texas used the DEFENDANTS' representation of the prices they charged wholesalers for the specified drugs. In the case of the specified retail pharmacy drugs, the DEFENDANTS falsely inflated their reports of the drug prices and costs so that Medicaid pharmacy providers would be paid excessive amounts and thus choose the specified retail pharmacy drugs over competing generic versions. The DEFENDANTS' false price representations were made directly to the States by the DEFENDANTS and through First Data Bank, the company that assembles drug price data for the State Medicaid programs.

7. The DEFENDANTS reported truthful prices for many drugs and the States' Medicaid programs were thus able to accurately estimate acquisition costs when paying claims for those drugs.

8. By using falsely inflated cost and price representations the DEFENDANTS created a "Spread" between the inflated acquisition cost that they caused the States to calculate and use for reimbursement purposes and the actual cost of the drug to the retail pharmacies. This "Spread", which constituted an unlawful financial inducement

arranged by the DEFENDANTS, directly benefitted the DEFENDANTS because it caused their Medicaid provider customers to order the DEFENDANTS' specified drugs instead of their competitors'. The DEFENDANTS thus duped the States'' Medicaid programs into paying claims for the specified drugs at inflated amounts in order to increase the DEFENDANTS' sales. The DEFENDANTS lied about the price and cost of their specified drugs in order to cause the States to expend Medicaid program dollars to unwittingly fund unlawful kickbacks to Medicaid providers.

9. The DEFENDANTS' wrongful exploitation of the States' Medicaid programs caused the UNITED STATES and the States' Medicaid programs to incur single damages in excess of Ten Million Dollars for which the UNITED STATES and States' Medicaid programs are entitled to recover treble damages plus up to Ten Thousand Dollars per false claim, interest, costs and attorneys' fees.

B. DRUG MANUFACTURERS' FALSE PRICE REPRESENTATIONS INVOLVING SPECIALIZED PHYSICIANS AND PHARMACIES

10. The DEFENDANTS made false representations of prices and costs for certain of their drugs and biologicals (hereinafter sometimes referred to as the "specified physician drugs"): directly to Medicare Carriers and Durable Medical Equipment Regional Carriers ("DMERC's") who approve and pay Medicare claims; directly to the States' Medicaid Pharmacy programs which approve and pay the States' Medicaid claims; and indirectly through drug price and cost reporting compendia including First Data Bank, Medical Economics, and Medi-Span. The DEFENDANTS knew that the Medicare and States' Medicaid programs intended to base their

payments of "reimbursement" for the specified physician drugs on reasonable estimations of cost. The Medicare and Medicaid programs utilized the prices reported by the DEFENDANTS in estimating costs. The DEFENDANTS marketed their specified physician drugs to specialized physicians [redacted], clinics and pharmacies (hereinafter referred to as "Physician Drug Providers"), including the Relator, through financial inducements, including but not limited to, reporting falsely inflated price and cost figures (thus creating a "Spread"), discounts, free goods and other financial incentives. The DEFENDANTS were in a position to mislead the Medicare and Medicaid programs because the DEFENDANTS often report truthful prices for their other drugs that are not the subject of this action. The DEFENDANTS thus wrongfully exploited the Medicare and States' Medicaid programs by causing them to pay Physician Drug Providers grossly inflated amounts that far exceeded a reasonable reimbursement amount based on an estimation of costs. This wrongful exploitation by DEFENDANTS caused the United States to incur single damages in excess of Ten Million Dollars for which the UNITED STATES and States' Medicaid programs are entitled to recover treble damages plus up to Ten Thousand Dollars per false claim, interest, costs and attorneys' fees.

SECTION NO. 2
THE PARTIES

11. The Plaintiff in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"),and its successor agency the

Centers for Medicare and Medicaid Services ("CMS") and The Bureau of Program Operations ("BPO") were agencies and instrumentalities of the UNITED STATES and their activities, operations and contracts in administering the Medicare program were paid from UNITED STATES' funds. The UNITED STATES and its subcontractors performing on behalf of the UNITED STATES provided Medicare benefits to qualified beneficiaries which included payment of claims for the prescription drugs specified herein manufactured by the DEFENDANTS and used the false and fraudulent price and cost representations made by the DEFENDANTS in approving and paying claims.

12. The States, United States Territories, and the District of Columbia provided Medicaid benefits to qualified recipients which included payment of claims for the prescription drugs specified herein manufactured by the DEFENDANTS and used the false and fraudulent price and cost representations made by the DEFENDANTS in approving and paying claims. A significant percentage (at least 50%) of said Medicaid reimbursement was paid from United States Government funds pursuant to 42 U.S.C. § 1396(b).

13. The Relator, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator's principal officers and directors include Zachary T. Bentley and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The Relator is a pharmacy and provides prescription drugs and biologicals specified in this Second Amended Complaint and has been a Medicare Part B supplier and a Florida Medicaid

provider. The Relator has direct and independent knowledge of the information, and is the "original source" of the information on which these allegations are based within the meaning of 31 U.S.C. §3730(e)(4)(A) and (B). The Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1). The information upon which these allegations are based was voluntarily provided by the Relator to the Federal Government prior to November 1996 and thereafter has been frequently supplemented by the Relator.

14. Ven-A-Care's principals were aware that Medicare and Medicaid reimbursed for drugs at amounts that were intended to be based on an estimation of cost and not provide for huge windfall profits at the GOVERNMENT's expense. Ven-A-Care attempted to alert the responsible state and Federal Government officials to the scheme being perpetrated by the DEFENDANTS. However, the government agencies lacked sufficient resources and expertise to adequately respond. Accordingly, the Relator commenced this action based upon its original source information.

15. [redacted]

16. [redacted]

17. [redacted]

18. DEFENDANT, DEY, INC. f/k/a DEY LABORATORIES, INC. ("DEY"), is a corporation organized under the laws of Delaware with its principal offices in Napa, California. At all times material to this civil action, DEY has transacted business in the Federal Judicial District of Massachusetts by, including but not limited to, selling directly or through wholesalers its specified prescription drugs specified herein in the District of Massachusetts knowing that the drugs would be supplied to Medicare beneficiaries and Medicaid recipients and for which claims would be paid from federal funds.

19. [redacted]

20. [redacted]

PAGES 12 THROUGH 15

WERE COMPLETELY REDACTED

WHICH INCLUDES PARAGRAPHS

21 THROUGH 29

[redacted]

30. [redacted]

31. Any and all acts alleged herein to have been committed by any or all of the DEFENDANTS were committed by each DEFENDANT'S parents, affiliates, subsidiaries, officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT.

SECTION NO. 3
JURISDICTION & VENUE

32. Jurisdiction is founded upon the Federal False Claims Act (the "Act"), 31 U.S.C. §3729-32, specifically 31 U.S.C. §3732, and also 28 U.S.C. §§1331, 1345.

33. Venue in the District of Massachusetts is appropriate under 31 U.S.C. §3732(a) and sufficient contacts exist for jurisdiction in that each of the DEFENDANTS transacted business in the District of Massachusetts by selling directly or through wholesalers their specified prescription drugs in the District of Massachusetts which the respective DEFENDANTS knew would be supplied to Medicare beneficiaries and Medicaid recipients and knew claims for reimbursement with respect to DEFENDANTS' specified prescription drugs would be made by Medicaid and Medicare providers.

34. A copy of the initial Complaint and this Second Amended Complaint and written disclosure of substantially all material evidence and information VEN-A-CARE possesses were served on the Government pursuant to Rule 4(i)(1)(A) and (B), Fed.R.Civ.P., prior to the filing of the initial Complaint and this Second Amended Complaint **in camera and under seal** by delivering a copy of the initial Complaint and this Second Amended Complaint, material evidence and information to the United States Attorney for the District of Massachusetts and by sending a copy of the initial Complaint and this Second Amended Complaint, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia.

SECTION NO. 4

HOW MEDICARE AND MEDICAID REIMBURSEMENT IS AFFECTED BY DRUG MANUFACTURERS' PRICE AND COST REPRESENTATIONS

35. Drug manufacturers, including the DEFENDANTS, the Medicare and Medicaid programs, drug price and cost reporting services, hospitals, pharmacies, physicians, wholesalers, third party payors and administrators (i.e. insurance companies), governmental health benefit plans (i.e. federal and state employees) and others involved in the health care industry communicate about drug prices and costs by describing the price and cost with terms such as:

a) Average Wholesale Price ("AWP")

b) Wholesaler Acquisition Cost ("WAC")

c) List Price

d) Direct Price ("DP")

e) Wholesale Net Price

36. Of the above terms, Average Wholesale Price, or AWP, is most utilized by the health care industry and by third party payors including the Medicare and Medicaid programs to describe the price of a drug sold to a retailer (i.e. Physicians, Hospitals and Pharmacies) who then provides the drug to its ultimate recipient.

37. During the time covered by this complaint until January 1, 1998, Medicare based its reimbursement for prescription drugs, including the drugs at issue, on the manufacturers' published AWP for patented ("single source") drugs as represented by the manufacturer, and at the median published AWP, as represented by the

manufacturers, for drugs with generic equivalents and for biologicals. Pursuant to Congressional investigation, and in an effort to arrive at reasonable Medicare drug reimbursement amounts, the Federal Government changed the Medicare drug reimbursement formula pursuant to the Balanced Budget Act of 1997. Thus, from January 1, 1998 until the present, Medicare has based its reimbursement for drugs at 95% of the published AWP for single source patented drugs as represented by the manufacturer, and at 95 % of the median published AWP, as represented by the manufacturers, for drugs with generic equivalents and for biologicals. Throughout the period covered by this complaint the United States Congress, CMS and the States' Medicaid programs have attempted to address the impact of drug costs on the Medicare and Medicaid programs, however, their efforts have been impeded by the inflated price and costs reports at issue in this action.

38. The States' Medicaid programs are required by 42 CFR 447.331 to reimburse providers at the provider's Estimated Acquisition Cost ("EAC"). CMS, which must approve all State reimbursement plans for prescription drugs, has approved approximately 38 state plans whose methodology for arriving at the provider's EAC includes discounting a percentage off of the published AWP prices. This discounting ranges from Alaska, whose state formula is AWP minus 5%, to Michigan, whose state formula is AWP minus 13.5 - 15.1 %. Nineteen states' formulas are AWP minus 10%. Texas uses direct drug manufacturers' prices representations. Six states' formulas are WAC plus a percentage or an AWP discount/WAC hybrid. The State of Delaware

bases reimbursement on the providers' actual acquisition cost ("AAC"). The balance of the states use a EAC/AWP discount mix.

39. The Office of Personnel Management administers health insurance for all federal employees. Benefits and reimbursements for prescription drugs are based upon the published AWP's as represented by the drug manufacturers.

40. The Department of Defense's CHAMPUS program, now known as Tricare, bases benefits and reimbursements for prescription drugs upon the published AWPs LP as represented by the drug manufacturers.

41. The Relator's investigation has determined that most private third party health insurers also use the published AWPs as represented by the drug manufacturers in establishing prices for prescription drug benefits.

42. The drug manufacturing industry, including the DEFENDANTS, uses various forms of media to publicize the prices and cost of their drugs including but not limited to:

a) Direct mailings or electronic communications (i.e. fax or e-mails) to hospitals, pharmacies, physicians, the States' Medicaid programs and the Medicare carriers;

b) Advertisements in bi-monthly medical publications, such as :

(i) *Medical Economics,* that is mailed bi-monthly to most physicians and hospitals, free of charge by its publisher; and

(ii) *Drug Topics*, that is mailed bi-monthly to most pharmacies and hospitals, free of charge by its publisher;

c) *PDR Generics* published annually by Medical Economics, Inc. who also publishes *The Physicians Desk Reference ("PDR")*

d) Advertisements provided directly to physicians and pharmacists by drug companies' representatives.

43. The Relator's information provided to the Government demonstrates the common and widespread use of the term "Average Wholesale Price" (AWP) to describe drug prices in a manner whereby interested parties can make decisions that are affected by price, including but not limited to:

a) Representative examples of advertisements routinely delivered by some of the DEFENDANTS and Non-Defendant drug manufacturers directly to individual State Medicaid programs that were delivered to the State of New Jersey's Medicaid Pharmacy Program.

b) Representative examples of advertisements routinely delivered by the DEFENDANTS and Non-Defendant drug manufacturers directly to individual Medicare carriers responsible for approving and paying Medicare claims in the States of Florida and Utah.

c) Representative examples of direct mail advertisements sent to the Relator by Non-Defendant drug companies expressing their respective drug prices in terms of AWP.

d) Representative examples of advertisements that the DEFENDANTS caused to be published in *Medical Economics* that express their respective drug prices in terms of AWP.

e) Representative examples of advertisements that the respective drug manufacturers caused to be published in *Drug Topics* that express their respective drug prices in terms of AWP.

f) Representative examples of the publisher's representations about the 1996 edition of *PDR Generics,* which contains representations about drugs at issue in this case including price and cost information expressed in terms of AWP. The advertisement also states that *PDR Generics* provides physicians and other health care professionals with "cost of therapy tables" that enable the physician to compare cost of therapies. The cost of therapies are based upon the manufacturers' published AWPs for the respective drugs.

44. Drug manufacturers including some of the DEFENDANTS also represent drug prices in terms of AWP when comparing the price and cost of their drugs to the prices and costs of their competitors' drugs. These comparisons of prices are promoted to physicians, pharmacists and hospitals touting that one company's drug is less costly than that of its competitors.

45. Medical Economics, Inc., the Hearst Corporation and Medi-Span are nationally recognized companies that specialize in gathering drug pricing and cost

information including Average Wholesale Price ("AWP"), Wholesaler Acquisition Cost ("WAC") and Direct Price ("DP").

46. Medical Economics, Inc. publishes annually a book entitled *Drug Topics Red Book* that expresses drug prices and costs in terms of AWP. Representative examples of *Drug Topics Red Book* for the years 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998 and 1999 contain approximately the following number of pages expressing drug prices and costs in terms of AWP:

a) 1991 - 605 pages

b) 1992 - 575 pages

c) 1993 - 542 pages

d) 1994 - 331 pages

e) 1995 - 369 pages

f) 1996 - 413 pages

g) 1997 - 454 pages

h) 1998 - 470 pages

i) 1999 - 454 pages

47. Medical Economics also provides addendums to the annual *Red Book* that express drug prices and costs in terms of AWP.

48. Representative excerpts of advisements contained in the annual *Red Book* publications for the years 1995, 1996, 1997, 1998 and 1999 include:

a) The 1995 advertisement describes the price information as "nationally recognized average wholesale prices (AWPs, direct prices and federally upper limited prices for prescription drugs)."

b) The 1996 advertisement states "nationally recognized Average Wholesale Prices (AWPs), Direct Prices and Federal Upper Limit prices for prescription drugs that help you make sure your prices are on-target."

c) The 1997 advertisement states "complete pricing information: AWPs, direct and suggested retail prices."

d) The 1998 advertisement states "RED BOOK is the first and only source of accurate, up-to-date product information, prices on prescription drugs, OTC items and reimbursable medical supplies and more!"

e) The 1999 advertisement states "nationally recognized Average Wholesale Prices (AWPs), Direct Prices and Federal Upper Limit prices for prescription drugs that help you make sure your prices are on-target."

49. Medical Economics, Inc. also publishes a monthly update that contains current packaging and pricing data expressed in terms of AWP on the most widely prescribed drugs in the United States together with any updated prices expressed in terms of AWP for new products.

50. The Relator's information provided to the Government reveals that approximately 90% of the Medicare carriers use the AWPs as represented in Medical Economics annual *Drug Tropics Red Book* publication and the *Red Book* monthly

updates in determining the reimbursement amounts for Medicare prescription drug claims.

51. Until 1997, the Hearst Corporation annually published through 1997, through its subsidiary First Data Bank, a book entitled *the Blue Book* that expressed drug prices and costs in terms of AWP. Representative examples of the *First Data Bank Blue Book* for the years 1990, 1991, 1992, 1993, 1994, 1995 and 1996 contain approximately the following number of pages expressing drug prices and costs in terms of AWP:

a) 1990 - 498 pages

b) 1991 - 492 pages

c) 1992 - 482 pages

d) 1993 - 402 pages

e) 1994 - 755 pages

f) 1995 - 391 pages

g) 1996 - 432 pages

52. First Data Bank ("FDB") is a nationally recognized company that specializes in collecting and publishing drug data including pricing. FDB currently provides prices and costs for approximately 80,000 different drugs, sizes and strengths expressed in terms of AWP and WAC through an electronic or automated service. More than 90% of the States' Medicaid Pharmacy programs utilized the AWPs and

WACs as communicated by First Data Bank's automated services in determining reimbursement amounts for Medicaid prescription drug claims.

53. First Data Bank also publishes a monthly update entitled "Price Alert" that expresses drug prices and costs in terms of AWP.

54. The monthly newsletter *Monthly Interest*, Vol. 6 No. 9, September 1991, published by First Data Bank was mailed to the States' Medicaid Pharmacy programs. The article entitled "Understanding AWP" describes in detail First Data Bank's methods for determining AWPs in order to insure the State Medicaid programs "that the AWP reflects reality."

55. Medi-Span provides drug prices and costs for approximately 60,000 drugs, sizes and strengths through an electronic or automated service. The Relator's investigation has determined that only the State of New York's Medicaid program uses Medi-Span's automated service in determining reimbursement amounts for New York Medicaid prescription drug claims. Medi-Span was acquired by the Hearst Corporation/First Data Bank.

56. First Data Bank, Medical Economics and Medi-Span all receive and rely upon the respective drug manufacturers', including the DEFENDANTS, representations of their drugs' prices and cost in determining the drug pricing data that they report.

57. First Data Bank, Medical Economics and Medi-Span all report drug prices that include a representation of the drugs' AWP.

58. The Relators investigation has determined that drug manufacturers including the DEFENDANTS provide First Data Bank, Medical Economics and Medi-Span with the specific prices and costs of their drugs and instructions, if necessary, expressed in a manner that allows the price reporting companies to establish the necessary pricing information for publication that is utilized by Medicare, Medicaid and others in determining reimbursements for prescription drugs.

59. The Relator's information is, during the time covered by this complaint, that:

a) Medical Economics/*RED BOOK* has defined AWP as the price a retail hospital or pharmacy pays if it purchases the drug from a wholesaler before a discount if any.

b) First Data Bank/*BLUE BOOK* has defined AWP as an average price which a wholesaler charges for a particular drug.

c) Medi-Span has defined AWP as the most common wholesaler price charged to the retailer or hospital.

60. A form entitled "New Product Submission Form" is provided by First Data Bank to drug manufacturers to transmit information including their prices to First Data Bank. The form permits drug manufacturers to submit prices expressed in terms of Wholesale (Distributor) Price, Direct Price and AWP Price.

61. A form entitled "Product Listing Verification" is provided by Medical Economics / *Red Book* to drug manufacturers to transmit information including their

prices to Medical Economics / *Red Book*. The form permits drug manufacturers to submit prices expressed in terms of AWP and WAC.

62. The Relator's information revealed that each of the DEFENDANTS had been the source of the price and cost information reported by First Data Bank and Medical Economics to the Medicare and States' Medicaid programs at all times at issue in this action. The Relator reported its information to the Government, including specific identification of representatives of First Data Bank and Medical Economics to whom such information was reported. Thereafter, the Government conducted an investigation which confirmed the information supplied by the Relator.

A. The Government's investigation revealed that each of the DEFENDANTS has repeatedly and systemically communicated with First Data Bank and Medical Economics for the express purpose of causing First Data Bank and Medical Economics to report prices and costs of the drugs at issue in this case in amounts set by the DEFENDANTS.

B. The Government's investigation secured documentary information between the DEFENDANTS and First Data Bank and Medical Economics wherein the DEFENDANTS caused specific prices and costs for their drugs to be reported by First Data Bank and Medical Economics.

63. The DEFENDANTS' fraudulent inflation of price and cost information to cause the Government to pay excessive reimbursement for the specified drugs at issue

is in stark contrast to the truthful representations that the DEFENDANTS make when they are not offering financial inducements to their customers.

64. Unlike the specialized physicians, clinics and pharmacies which receive the financial inducements for ordering the drugs at issue in this action, most providers do not receive grossly excessive reimbursements for prescribing the majority of other drugs and instead rely on the manufacturers' truthful representations of price and cost in an effort to minimize the cost of drugs to their patients.

65. The vast majority of drug manufacturers, including the DEFENDANTS, are truthful when representing prices and costs of all or most drugs, except for the drugs at issue in this case.

SECTION NO. 5
THE ROLE OF THE DRUG WHOLESALER

66. The majority of the DEFENDANTS' drugs, including the specified drugs at issue in this action, are distributed through drug wholesalers who resell and distribute the drugs to hospitals, pharmacies, physicians and clinics.

67. Four companies, McKesson Drug, Cardinal, Bergen Brunswig and Ameri-Source, comprise approximately eighty (80%) of the 53 billion dollar annual wholesale drug market. Wholesalers generally sell to any person or entity (i.e. pharmacies, physicians and hospitals) who can lawfully purchase prescription drugs.

68. Wholesalers purchase the specified drugs at prices that are unilaterally set and controlled by the DEFENDANTS. The wholesalers in turn add a percentage (commonly referred to as an "up-charge") to the price to cover the wholesaler's

expenses such as warehousing, delivery, billing and collections and provides a profit. The percentage of up-charge is negotiated between the pharmacy and the wholesaler and is usually based on the pharmacy's purchasing volume. By way of example, the Relator's up-charge from McKesson is 6.5%.

69. The DEFENDANTS also sell directly and indirectly to hospitals and retail pharmacies through group purchasing organizations (" GPO's") and buying groups. GPO's and buying groups represent smaller providers and provide members with lower costs by negotiating prices for specific drugs from the manufacturers. The GPO or buying group member is able to purchase the drugs at the GPO's or buying group's negotiated price either directly from the manufacturer or from a wholesaler that has a "charge-back" agreement with the specific manufacturer.

70. The DEFENDANTS' "charge-back" arrangements with wholesalers allows the DEFENDANTS to sell drugs, including some of the drugs at issue in this case, to the wholesalers at a fictitiously inflated price. When a wholesaler sells a drug, the price of which has been negotiated with a GPO or buying group, the wholesaler is credited by the DEFENDANT for the difference between the false price and the true price to the DEFENDANTS' customer plus the agreed "up-charge" for the wholesaler. The DEFENDANTS' exploitation of the "charge-back" scheme allows the DEFENDANTS to control prices charged by wholesalers while fictitiously reporting inflated wholesaler cost.

71. The "charge-back" scheme is illustrated by the following example of the drug, [redacted], manufactured by DEFENDANT [redacted] and wholesaled through McKesson Drug Co. ("McKesson"):

a) McKesson's March 2000 published wholesale price for [redacted], is $29.48;

b) Ven-A-Care is a member of the Servall buying group. Servall is a McKesson sponsored buying group that is available to any retail pharmacy that purchases prescription drugs from McKesson;

c) Ven-A-Care's Servall buying group's price for [redacted], is $7.93. Therefore, Ven-A-Care can purchase a bottle of [redacted] from McKesson for $8.45 which includes McKesson's 6.5% up-charge to Ven-A- Care. This is $21.03 less than McKesson purportedly paid DEFENDANT [redacted]

d) McKesson claims a "charge-back" from DEFENDANT [redacted] of $21.55 which represents the difference in price from what McKesson paid ($29.48) versus the price McKesson sold it to Ven-A-Care ($7.93), not including McKesson's up-charge.

72. In order to monitor the wholesalers' compliance, the DEFENDANTS require all drug wholesalers to periodically (generally quarterly) report back to the

DEFENDANTS all prescription drug sales by NDC number, provider name and sales price.

73. A representative example of this practice was demonstrated when Ven-A-Care was informed by a [redacted] sales representative that [redacted] and other drug manufacturers consider this information vital in determining how and where to market their prescription drugs. The [redacted] representative informed VAC that [redacted] prepared reports for every sales representative based on the information compiled from all wholesalers' reports and that the [redacted] report was broken down by postal zip code, provider, NDC number, quantity and sales prices.

SECTION NO. 6

BACKGROUND OF HOW UNITED STATES' MONIES ARE PAID FOR DRUG CLAIMS UNDER "PART B" OF THE MEDICARE PROGRAM

74. The Department of Health and Human Services ("HHS"), through the Centers for Medicare and Medicaid Services ("CMS"), provides health insurance benefits to aged and disabled Americans pursuant to the provisions of the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq.

75. The Medicare program provides covered health care benefits to certain targeted populations such as those persons who are over age 65, persons who are disabled, and persons who have end stage renal disease.

76. The Medicare program is divided into two distinct parts: (A) Medicare Part A (Hospital Insurance for the Aged and Disabled) which covers services and goods furnished by hospitals, home health agencies, hospices, and skilled nursing facilities;

and (B) Medicare Part B (Supplementary Medical Insurance for the Aged and Disabled) which covers physician services, and a range of other noninstitutional services, such as durable medical equipment ("DME"), oxygen concentrators, diagnostic laboratory tests, X-rays, and certain limited drug products and supplies.

77. With respect to the specified physician drugs, this case focuses on the Medicare program's limited benefit for drugs which are provided either: (A) incident to a physician's service and cannot be self administered; or, (B) in conjunction with the medical necessity of a pump or nebulizer or other DME device payable under Medicare's DME benefit. Because this limited drug benefit is provided on an "incident to" a physician's service basis or in conjunction with the medical necessity of a DME device, Congress' statutes and the corresponding HHS regulations and CMS policies have sought to limit Medicare's payments for claims for the drugs at issue to a reasonable amount based upon the cost of the drug. This is due, in part, to the fact that the Medicare program is already paying for the physicians' professional fees and for the covered DME equipment. The exorbitant profits created by the DEFENDANTS' false price and cost representations have totally thwarted the fundamental requirements of the Medicare Program (and States' Medicaid programs) that payment of claims for the specified drugs be limited to reasonable amounts to cover the added cost of the drugs.

78. CMS administers the Medicare program. CMS awards cost-reimbursement contracts to private companies (hereinafter referred to as "Carriers") to

evaluate and to process Medicare beneficiaries' claims for payment on behalf of CMS. Under Part A, CMS refers to contractors as "intermediaries". Under Part B, CMS refers to contractors as "carriers" and durable medical equipment regional carriers ("DMERCs"). Under Part B, CMS pays the carriers and the DMERCs to process claims for covered benefits supplied to eligible beneficiaries and to make payments to the providers or to the Medicare beneficiaries for the covered services rendered under Medicare Part B. 42 U.S.C. §1395(j) et seq.

79. Congress has mandated that the Medicare program pay no more than eighty percent (80%) of: (1) the reasonable cost of drugs covered under Part B pharmaceutical claims from federal funds through 1997 and (2) no more than 95% of the drug's Average Wholesale Price, after 1997. 42 U.S.C. §1395(l) et seq.

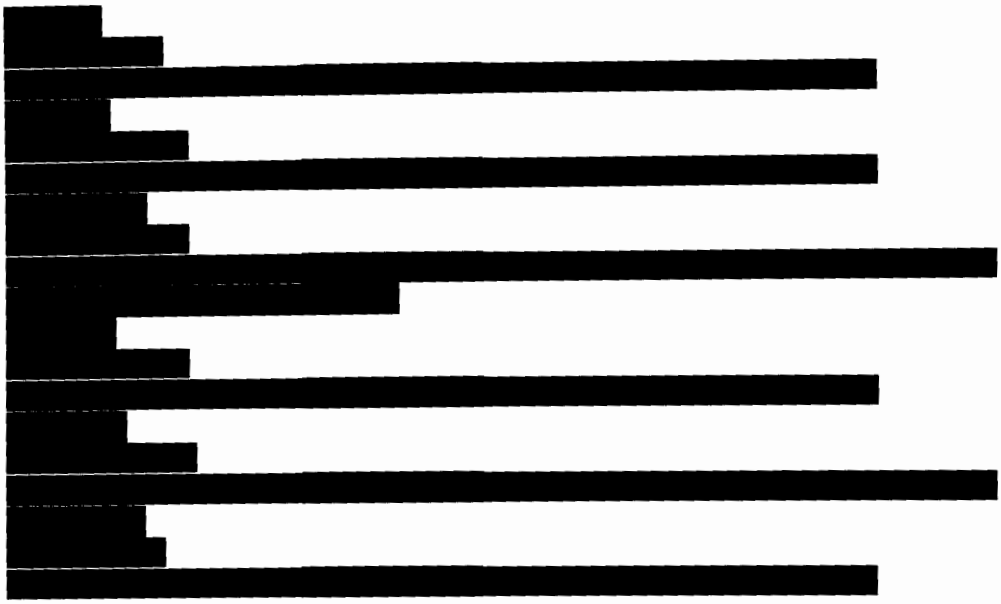
80. Medicare Regulation 42 CFR, §405.517, effective January 1, 1992, sets out the methodology to determine the reasonable charge for payment of claims for drugs and biologicals. The methodology for single source drugs is based on the lower of estimated acquisition cost or the national average wholesale price of the drug. The methodology for multiple source drugs is based on the lower of the estimated acquisition cost or the wholesale price that is the median price for all sources of the generic form of the drug. The instructions state that the estimated acquisition cost is to be based on surveys of actual invoice prices of drugs paid by the providers. The regulation also states that other factors such as inventory, waste and spoilage may be considered in calculating the estimated acquisition cost of the drug but does not provide

for profit on the drug itself. For purposes of reimbursement, CMS reimburses biologicals under the same methodology as other drugs. Claims are to be paid at the lesser of an estimated amount based upon average wholesale price ("AWP") or actual acquisition cost (taking into consideration inventory cost and waste but including no profit on the drug itself).

81. The Medicare program has been unable to determine actual acquisition costs for the drugs at issue in this case. Therefore, until January 1, 1998, Medicare paid claims based upon the average wholesale price for single source patented drugs as represented by the manufacturer, and at the median average wholesale price, as represented by the manufacturers, for drugs with generic equivalents and for biologicals. From January 1, 1998 until the present, Medicare has paid claims based upon 95% of the average wholesale price for single source patented drugs as represented by the manufacturer, and at 95% of the median average wholesale price, as represented by the manufacturers, for drugs with generic equivalents and for biologicals.

82. The following is an example of how in 1997 the Medicare Carriers established reimbursement for the generic [redacted] First, the Carrier references the 1997 *Drug Topics Red Book* listing for [redacted]. Second, the Carrier arrays the listings from the most expensive to the least expensive of all the manufacturers' generics (in this case DEFENDANT [redacted]

[redacted] is the Brand so it is not included) that list a 100 mg. size (20 mg/ml, 5 ml = 100mg.) as follows:



Third, the Carrier finds the median AWP. In this instance the median is between [redacted] at $141.00 ea. and [redacted] at $136.49. The Relators investigation has determined that some Carriers choose the higher listing of the median and some choose the lower.

83. Part B drug claims are submitted either in hard copy form or through an electronic claims filing procedure.

84. Providers submit claims for payment to the Medicare program for the specified drugs at issue in this case using CMS's Common Procedure Coding System ("HCPCS"). The HCPCS system for pharmaceuticals is a 5 digit alphanumeric code, such as [redacted]

85. CMS requires all Part B Carriers and the DMERC's to report to CMS Central quarterly claims activity by HCPCS Code for all drugs submitted by providers for reimbursement by the Medicare program. This quarterly data collected by CMS Central from all the Part B Carriers and the DMERCs is summarized in a report known as the Part B Extract and Summary System ("BESS") or Bess Reports.

86. Beneficiaries' claims are processed by the Carriers and the DMERC's as either "assigned", those claims for which payment is made directly to the provider, or "unassigned", those claims for which payment is made directly to the beneficiaries.

87. All or nearly all drug claims for the charges at issue are made on an assigned basis.

88. During the early 90's the Medicare Carriers' attempted to survey physicians' actual invoice prices paid for drugs to comply with the regulation 42 CFR §405.517 but were stopped by a complaint filed by the American Society of Clinical Oncologists ("ASCO") with the Executive Office of Management and Budget asserting that the Paperwork Reduction Act had been violated. A subsequent effort by CMS to design a new survey to determine physicians' actual invoice costs was also stopped by ASCO. ASCO complained that the actual prices being paid were discounts and confidential in nature and that the survey had other flaws.

89. At all times at issue in this case, the Medicare program used the drug price and cost information represented by the DEFENDANTS to determine reimbursement amounts.

SECTION NO. 7

BACKGROUND OF HOW UNITED STATES' MONIES ARE PAID FOR DRUG CLAIMS UNDER THE STATES' MEDICAID PROGRAMS

90. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq.

91. Benefits for drugs are optional but all states have opted to provide Medicaid drug reimbursement coverage.

92. The federal portion of States' Medicaid payments, Federal Medical Assistance Percentage ("FMAP") is a percentage amount based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. By example, Florida's FMAP contributed by the United States in 1995 was 56.28%.

93. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. §1396a(a)(30)(A).

94. State Health Plans must, in part, provide for payment of claims for prescription drugs pursuant to a formula approved by the Secretary of HHS which determines the maximum allowable claim amount for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement based upon

an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR 447.331.

95. CMS has approved approximately 38 state plans whose methodology for arriving at a provider's Estimated Acquisition Cost ("EAC") as required by 42 CFR 447.331 includes discounting a percentage off of the AWP prices, separately for each covered drug, as computed by or collected by and published by First Data Bank. This discounting ranges from Alaska, whose state formula is AWP minus 5%, to Michigan, whose state formula is AWP minus 13.5 - 15.1 %. Nineteen CMS approved states' formulas are on a basis of AWP minus 10%. Seven states' formulas are WAC plus a percentage or an AWP discount/WAC hybrid. The State of Florida's formula is WAC plus 7%. The State of Delaware bases reimbursement on AAC.

96. The Food and Drug Administration ("FDA") assigns National Drug Codes, called NDC numbers, to identify each individual manufacturer and its drugs' strengths and sizes. NDC numbers are eleven digits, with the first five digits identifying the manufacturer or labeler, the next four digits identifying the product and the last two digits identifying the package size.

97. Providers are required to utilize the FDA's NDC numbers when submitting claims for reimbursement for drugs to the States' Medicaid programs.

98. The vast majority of States award cost-reimbursement contracts to private companies to evaluate and process Medicaid recipients' claims for payment. The States refer to these contractors as fiscal agents.

99. Prescription drug claims are submitted either in hard copy form or through an electronic claims filing procedure.

100. At all times at issue in this case, all of the States' Medicaid programs used the drug price and cost information represented by the DEFENDANTS to determine reimbursement amounts.

101. CMS has approved state plans whose methodology formulae for arriving at a pharmacy's estimated acquisition cost as required by 42 CFR 447.331 includes:

a. discounting a percentage off of the AWP prices as computed by or collected by and published by First Data Bank ;

b. adding a percentage to the WAC prices as computed by or collected by and published by First Data Bank ; and,

c. requiring the drug companies, including the DEFENDANTS, to certify their prices directly in writing to the Texas Medicaid Vendor Drug Program.

102. The HCFA approved State plans for the WAC STATES at issue are:

	Drug	Dispensing Fee
Alabama	WAC+9.2%	$5.40
Colorado	lesser of AWP-10% or WAC+18%	$4.08
Florida	WAC+7%	$4.23
Maryland	WAC+10%	$4.21
Massachusetts	WAC+10%	$3.00
Ohio	WAC+11%	$3.70
Rhode Island	WAC+5%	$2.85-$3.40

103. The Texas Medicaid Program has gone to exceptional lengths to verify that drug manufacturers, including the DEFENDANTS, provide truthful price and cost information for reimbursement purposes. The Texas Medicaid authorities, acting pursuant to 25 Texas Administrative Code 35.801, required the DEFENDANTS to certify, in writing, the accuracy of their price and cost representations as a condition to their drugs being covered for reimbursement. The Relator's investigation has revealed that each of the DEFENDANTS, when responding to Texas about their specified drugs, either affirmatively lied about their true prices, or omitted material information in order to mislead the Texas Medicaid officials.

104. The State of Texas pays reimbursement for drugs covered by its Vendor Drug Program at the lesser of the provider's usual and customary charge or Estimated Acquisition Cost ("EAC"). In Texas' Pharmacy Provider Handbook, EAC is defined as

either the Wholesale Estimated Acquisition Cost ("WEAC") or the Direct Estimated Acquisition Cost ("DEAC"). WEAC is the estimated price paid by providers purchasing a drug from a wholesaler. DEAC is the estimated price paid by a provider purchasing the drug directly from the drug's manufacturer.

105. The State of Texas required the DEFENDANTS to complete a specific form regarding the prices of their drugs. Immediately before the required signature by the DEFENDANTS' representatives is the following language:

> I hereby certify that the information submitted is correct to the best of my knowledge . . . I also agree to inform the Texas Department of Health of any changes in . . . price . . . within fifteen (15) days of such change.

Attached hereto as **Exhibit "1"** is a true and correct copy of the current certification used by the Texas Medicaid Vendor Drug Program.

106. Congress has attempted to assist the States' Medicaid programs in limiting reimbursement amounts for certain generic prescription drugs to a reasonable estimate of acquisition cost by empowering CMS to set a Federal Upper Limit ("FUL") for drugs paid for by the Medicaid programs. Under the plan, CMS may impose a FUL on any generic drug if:

a. All formulations of the drug have been evaluated as therapeutically equivalent by the FDA;

b. At least three (3) companies list their drugs in current published compendia with their cost; and

c. If the above criteria are met, the drugs are available for sale nationally.

107. CMS then finds the least costly generic as listed in all available national compendia that can be purchased by pharmacies and multiplies this amount by 150%. The product then becomes the FUL for all manufacturers' generic form of the drug or the maximum amount a State Medicaid program can pay.

108. Pharmacies are reimbursed for prescription drugs by the States' Medicaid programs in accordance with:

i) the State's CMS approved plan (i.e. Massachusetts' WAC+ 10%);

ii) the pharmacies usual and customary charges to the general public; or,

iii) the Federal Upper Limit ("FUL") plus a reasonable professional or dispensing fee.

109. First Data Bank receives and uses the drug manufacturers', including the DEFENDANTS', representations of their drug prices and costs including the prices at which the DEFENDANTS sell their drugs to wholesalers (WAC) in determining the drug pricing data that they report to the States.

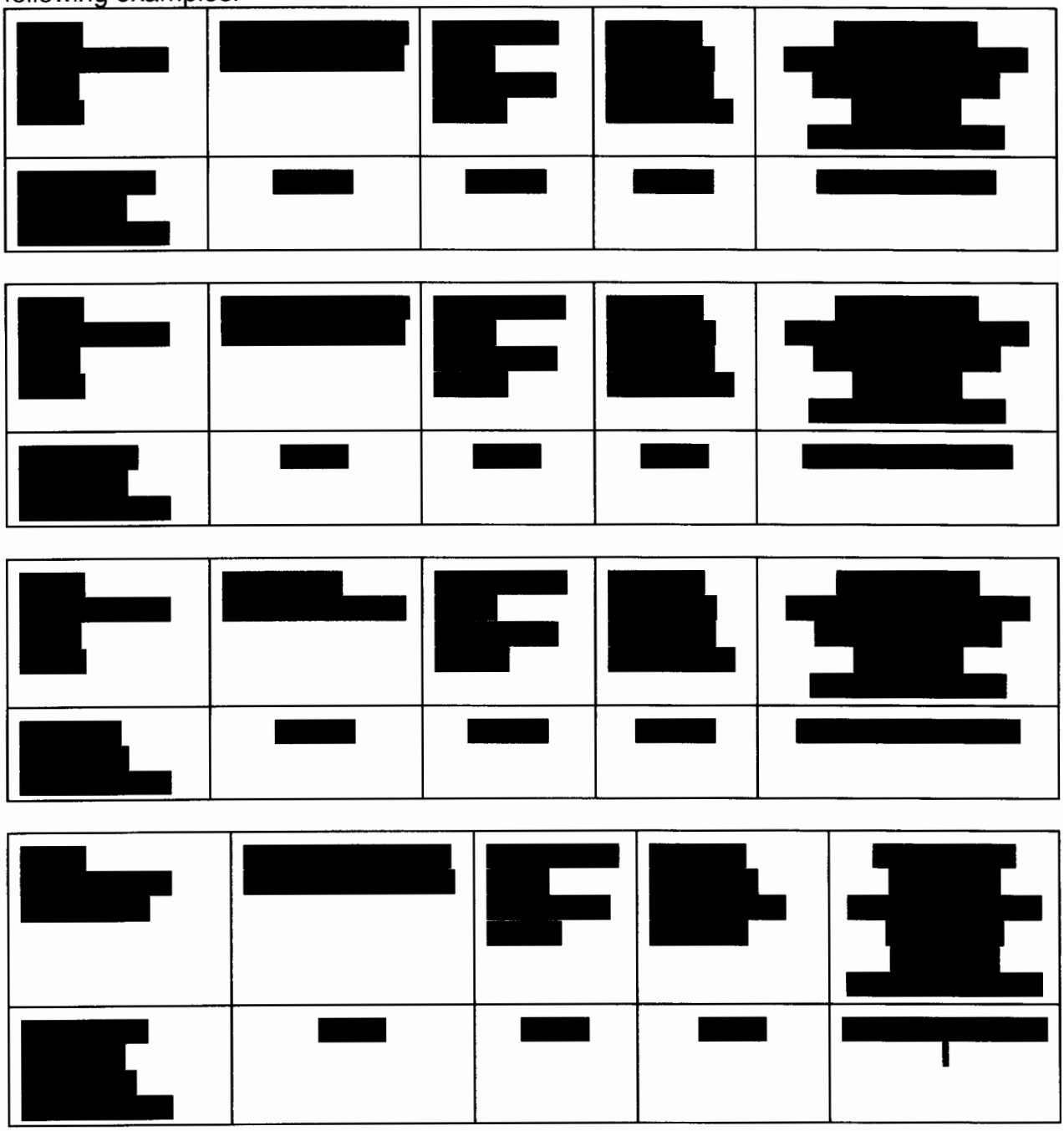
110. The Relator's investigation has determined that the DEFENDANTS provide First Data Bank with either the WAC price of its drugs or instructions, if necessary, expressed in a manner that allows First Data Bank to establish the WAC.

111. During the time covered by this complaint, First Data Bank has defined WAC as "wholesaler acquisition cost" for a particular drug. A form entitled "New Product Submission Form" is provided by First Data Bank to drug manufacturers, including the DEFENDANTS, to transmit information, including their prices, to First Data Bank. The form permits drug manufacturers to submit prices expressed in terms of Wholesale (Distributor) Price, Direct Price and AWP Price. Attached hereto is true and exact copy of said form as **Exhibit "2"**.

112. The Relator's information revealed that each of the DEFENDANTS had been the source of the price and cost information which was reported by First Data Bank to the States' Medicaid programs at all times at issue in this action. The Relator reported its information to the Government, including specific identification of representatives of First Data Bank to whom such information was reported.

113. The States' Medicaid programs also receive price and cost representations directly from the DEFENDANTS and use them to confirm the accuracy of price and cost in computing reimbursement amounts. Attached hereto as Composite **Exhibit "3"** are true and correct copies of price representations made by DEFENDANTS [redacted] to the State of Florida Medicaid Pharmacy Program on or about December 20, 1994 and September 26, 1994. Attached hereto as **Exhibit "4"** is a true and correct copy of price representations provided to Texas Medicaid by DEFENDANT [redacted] on or about March 6, 1997.

114. The importance that drug manufacturers represent truthful costs and prices and how these representations affect reimbursements is demonstrated by the following examples:



SECTION NO. 8
THE FALSE CLAIMS SCHEME

a. A description of the False Claims Scheme.

115. The DEFENDANTS are each liable under the False Claims Act because they caused the Medicare and the Medicaid Programs to pay claims for certain of their prescription drugs in exorbitant amounts, far in excess of the reasonable reimbursement permitted under the applicable statutes and regulations. The DEFENDANTS manufactured and/or distributed the specified prescription drugs in this action and sold the specified prescription drugs either directly to pharmacies, physicians, clinics and others or indirectly through such intermediaries as wholesalers and group purchasing organizations. The false claims for excessive reimbursement were then submitted to the Medicare and the States' Medicaid programs by the DEFENDANTS through their false price and cost statements. The Providers thereby received a windfall financial benefit in the amount by which the Government's approved "reimbursement" exceeded a reasonable estimate of acquisition cost.

116. The DEFENDANTS also caused the submission of false claims by actively marketing their specified drugs to Providers by the use of financial inducements created by "the spread" between the DEFENDANTS' true costs and prices to their customers and the Medicare and the States' Medicaid programs reimbursements based on the DEFENDANTS' falsely inflated costs and prices reported to Medicare and the States' Medicaid programs and their subcontractors. The financial inducements were in many cases enhanced by additional inducements such as free goods, discounts, rebates, direct money payments, off invoice pricing and deceptive invoicing.

117. The DEFENDANTS knew that the Medicare and States' Medicaid programs would not pay or approve claims for the specified drugs if it were disclosed to the Medicare and States' Medicaid programs that said claims were for amounts that included illegal remuneration prohibited by the anti-kickback statutes, 42 U.S.C. §1320a-7b(b)(2) and 1395nn(a)(1)(B).

118. The DEFENDANTS also knew that the Providers, in presenting claims for the specified drugs to the Medicare and States' Medicaid programs, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2) and 1395nn(a)(1)(B).

119. The DEFENDANTS each carried out their scheme to defraud the Government by knowingly providing false and misleading price and cost information to the Medicare and Medicaid programs so that the Providers would be reimbursed in excessive amounts and thus be financially induced to prescribe and purchase the DEFENDANTS' specified drugs. The DEFENDANTS thus each participated in a fraudulent scheme to cause the Government to pay and approve false claims in excessive amounts.

120. The claims in question are each false claims under the False Claims Act, in part, because they were each supported by, and the payment amount determined due to the Government's use of, the false and misleading price and cost information provided by the DEFENDANTS in connection with their respective specified drugs. The false and misleading price and cost information provided by the DEFENDANTS was used in setting Medicare and Medicaid reimbursement amounts and each DEFENDANT acted knowingly, as defined in the False Claims Act, in providing the

false and misleading price and cost information that caused the Government to pay claims for the DEFENDANTS' drugs in excessive amounts. The price and cost information provided by the DEFENDANTS was provided to cause the Government to pay amounts based on the information and thus constitutes claims submitted to the Government.

121. The false claims at issue in this action were each submitted to the Medicare and Medicaid programs by or on behalf of, Providers that sought and received payment in excessive amounts because of false and misleading price and cost representations made by the DEFENDANTS directly or indirectly to the Medicare and Medicaid programs. The specific false claims are thus each and every claim submitted to the Medicare or Medicaid program for which the payment amount was determined by use, in whole or to any degree, of the false and misleading price representations of the DEFENDANTS. The false claims at issue number in the tens of thousands and each claim is in the possession of a state's Medicaid program or Medicare Carrier to which it was submitted. The Relator has identified the specific false claims to the Government by providing the truthful prices concealed from the Government by the DEFENDANTS for each drug, providing information about the DEFENDANTS' exploitation of financial inducements to induce utilization of the specified drugs and specific identification information about the prescription drugs and the specific false price representations in question from which the Relator and the Government identified the specific false claims.

122. The damages sought herein include, but are not limited to, those arising from the false claims for the specified drugs set out in Sections 8 through 22 and

elsewhere throughout this Second Amended Complaint. The false claims for the specified drugs set out herein are alleged to meet the specificity and particularity requirements for pleading under the Federal Rules of Civil Procedure. The damages sought herein encompass all damages and penalties recoverable due to the false claim scheme of the DEFENDANTS alleged herein relating to all drugs of all sizes about which false price and cost representations or records were used in connection with, considered or made available in, caused, aided or otherwise affected the presentment, payment or approval of false claims. These claims also encompass recovery of the funds paid for false claims due to the DEFENDANTS' false drug price and cost representations, regardless of the Government program that actually expended the funds, the person or entity that ultimately received the funds or the person or entity from which the United States ultimately recovers the funds.

b. The DEFENDANTS Each Acted Knowingly

123. The DEFENDANTS are prohibited by the False Claims Act from making false representations in connection with claims for Government funds, are required by the Food and Drug Act to report true prices and are prohibited by the Medicare and Medicaid Anti-Kickback laws from arranging financial inducements for providers.

124. The patients, Medicare and the States' Medicaid programs were not aware of the prices actually paid for the specified drugs by the pharmacies presenting the claims for payment. The DEFENDANTS concealed from Medicare and the States' Medicaid programs price reductions occurring due to competition in the marketplace and falsely or fraudulently represented drug prices that far exceeded the truthful prices.

125. At all times material to this action, each of the DEFENDANTS acted "knowingly" as that term is defined at 31 U.S.C. §3729(b) by:

a) Causing the presentation of false or fraudulent claims for payment or approval by Medicare and/or the States' Medicaid programs, and

b) Making or using false statements or records for the purpose of getting false or fraudulent claims approved or paid by Medicare and/or the States' Medicaid programs.

126. The DEFENDANTS were clearly placed on notice that their conduct would cause Medicare and/or the States' Medicaid programs to pay claims for the specified drugs in amounts exceeding that permitted by applicable law, in part, because:

a) Each of the DEFENDANTS was on notice of federal statutes and regulations limiting payment of Medicare and/or Medicaid claims for the specified drugs to an amount necessary to cover the cost of the drug.

b) Each of the DEFENDANTS was on notice that the Medicare program and the States' Medicaid programs were not authorized or permitted by applicable law to pay claims for the specified drugs in excessive amounts.

c) Each of the DEFENDANTS was on notice that federal statutes and regulations prohibited it from making misleading representations about the specified drugs, including misleading price or cost representations.

127. Each of the DEFENDANTS was on notice that federal statutes and regulations governing food and drugs prohibited it from making misleading

representations about the specified drugs, including misleading price or cost representations, in part, because:

a) Each of the DEFENDANTS is required to comply with the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 et. seq., and the regulations promulgated pursuant thereto.

b) The price and cost representations about the specified drugs constitute advertising that is included in the "labeling" provisions of the Federal Food, Drug and Cosmetic Act and related regulations. 21 U.S.C. §§321; 352.

c) Each of the DEFENDANTS is prohibited from disseminating any information about its prices or costs of the specified drugs that is "false or misleading in any particular . . ." 21 U.S.C. §§352(a).

d) Each of the DEFENDANTS was on notice that it possessed a duty to assure that representations about prices and costs of the specified drugs were not misleading, taking into account:

> . . . not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling or advertising fails to reveal facts material in light of such representations.

21 U.S.C. §321(a) .

e) The DEFENDANTS can and do make truthful representations of wholesaler prices for most of their other drugs.

128. Each DEFENDANT was on notice that it was prohibited by federal statutes from paying or causing the payment of, directly or indirectly, money or other financial benefit to induce its customers to order the specified drugs when the Medicare

or States' Medicaid programs would be paying claims. 42 U.S.C. §1320a-7b(b)(2) and 42 U.S.C. §1395nn(a)(1)(B).

129. Notwithstanding the DEFENDANTS' knowledge that the Government used the DEFENDANTS' representations of price and cost and their knowledge of the applicable statutory requirements and prohibitions, each of the DEFENDANTS repeatedly, systematically and falsely reported inflated wholesaler prices as specified in Sections 9 through 21.

c. The DEFENDANTS directly benefitted through increased sales.

130. The DEFENDANTS benefitted directly from their false pricing scheme by maximizing their products' sales volume while capturing market share. An example of how the DEFENDANTS directly benefit from their false pricing scheme is demonstrated by data for the first quarter of 1997 from the State of Florida's Medicaid program setting out Florida Medicaid's reimbursements paid to pharmacies for the drug Albuterol Sulfate, 0.083% Solution ("Albuterol"), by DEFENDANTS DEY and [redacted] versus their competing manufacturers [redacted].

131. Albuterol is a prescription drug which is administered by inhalation and is used for the treatment of many respiratory illnesses. First quarter 1997 reimbursement data from the State of Florida's Medicaid program demonstrates that the wider "the Spread" between the true cost paid by providers versus the reimbursement paid by Medicaid the more a specific manufacturer's product will be utilized instead of a competitor's product. The DEFENDANTS [redacted] and DEY and the pharmaceutical manufacturers [redacted], have all made representations of Wholesaler Acquisition Cost to the State of Florida as set out in the chart below. As a

direct result of the false representations of prices and costs, the DEFENDANTS [redacted] and DEY caused the State of Florida's Medicaid program to unwittingly pay more than one million dollars for the first quarter of 1997 over the reasonable reimbursement amounts which the State intended to pay. The chart further sets out the number of reimbursed claims, VEN-A-CARE's cost per ml and "the Spread" between Medicaid reimbursement and true cost. A review of the chart clearly demonstrates that the vast majority of providers utilize the manufacturer's pharmaceutical with the greatest "Spread" between the true Wholesaler Acquisition Cost and the inflated false Wholesaler Acquisition Cost reported by the pharmaceutical manufacturer.

FALSE PRICING SCHEME - "THE SPREAD"

FLORIDA MEDICAID REIMBURSEMENT (1st Quarter 1997)
ALBUTEROL SULFATE SOLUTION 0.083%

Manufacturer	VAC's Cost per ml	Florida Medicaid Reimbursement per ml	The Spread	# of claims	Reimbursement paid by Florida Medicaid
[redacted]	$0.09	$0.3590	$0.269	12,673	$763,595.42
Dey	$0.10	$0.3531	$0.2531	9,792	$707,220.50
[redacted]	$0.10	$0.2138	$0.1138	102	$4,981.86
[redacted]	N/A	$0.1787	**	19	$1,278.08
TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA MEDICAID PROGRAM (January 1 through March 31, 1997)					$1,477,075.86

** The affect on the Medicaid program of the use of the spread to falsify claims is evidenced by the fact that [redacted] and DEY's customers will receive a greater windfall profit by buying DEY's or [redacted] product than the customers could receive if [redacted] gave the same product to them free of charge.

132. The grossly inflated payments unwittingly made by the States' Medicaid programs not only served as an inducement to providers to purchase a particular manufacturer's product but also served to drive over-utilization. The Relator, prior to filing the Complaint, surveyed three national pharmacy providers of Albuterol to determine their business practices for their sales of Albuterol to the Medicare and States' Medicaid programs. The Relator's principals used positions in an affiliated home health care company to pose as an interested customer. The Relator determined that the payment of kickbacks and/or split fees were common place between the pharmacies and home health care companies who could provide the pharmacies with patient referrals. One marketing scheme offered by one of the pharmacies was the automatic shipping of refills of Albuterol every month without verifying continuing need with the patient or physician in order to maximize the sales of Albuterol and reimbursement.

d. The DEFENDANTS' False Claim Scheme deprived the Government of the protection of The Federal Upper Limits ("FUL").

133. A representative example of the DEFENDANTS' efforts to deprive the Government of the benefit of the Federal Upper Limit, described at ¶ 106 herein), involves the drug [redacted]. In a letter dated November 7, 1996, DEFENDANT [redacted] made false price representations about the company's drug [redacted] to the State of Florida Medicaid Agency (Attached hereto as **Exhibit "5"** is a true and correct copy of said letter). Application of Florida's methodology of WAC plus 7%, to the prices represented by DEFENDANT [redacted] would have resulted in

reimbursement for [redacted]), of $59.65 (WAC = $55.75 + 7% = $59.65), plus the professional dispensing fee. However, [redacted] falls under the FUL program and its reimbursement was limited as of January, 1997, to $0.0464 per 50mg tablet or $4.64 per one hundred (100) 50mg tablets.

134. After having been alerted to the false claim scheme by the Relator, representatives of the State of Florida's Medicaid program refused to cover DEFENDANT [redacted] until such time as the State received from DEFENDANT [redacted] what the State considered to be DEFENDANT [redacted] truthful prices for [redacted]. The fact that Florida was not covering DEFENDANT [redacted] led to complaints to DEFENDANT [redacted] from pharmacies in Florida who had dispensed DEFENDANT [redacted] to Florida Medicaid recipients and who were receiving denials for payment by Unisys, the State's fiscal agent.

135. Approximately one month later, a State of Florida official received a telephone call from a person who stated he represented DEFENDANT [redacted] and requested immediate coverage of [redacted]. The Florida Medicaid official stated she would not cover the drug unless she received truthful prices. The person who represented DEFENDANT [redacted] stated words to the effect, "What does it matter? This drug is covered by the FUL program". The Florida official stated that it did matter as it could affect not only the reimbursement amount the State paid for [redacted] but also, if all manufacturers followed DEFENDANT [redacted] course and

conduct of making false pricing representations, it would cause the entire FUL program to be set at inflated amounts and completely frustrate the Government policy implemented by the FUL program.

136. Only when it became clear to DEFENDANT [redacted] representative that the Florida official was standing her ground, did DEFENDANT [redacted] provide a written disclosure dated December 5, 1996, of the truthful prices, (Attached hereto as **Exhibit "6"** is a true and exact copy of said letter). Applying Florida's Medicaid reimbursement methodology to DEFENDANT [redacted] truthful prices, the State pays $4.24 for one hundred (100) 50mg [redacted] tablets (WAC $3.96 + 7% = $4.24). The truthful prices saved the U.S. Government and the State of Florida $0.40 for each one hundred 50mg tablets.

137. The persistence of the Florida Medicaid representatives curtailed DEFENDANT [redacted] from circumventing the protections of the FUL program and caused DEFENDANT [redacted] to report a truthful WAC to First Data Bank. The following table summarizes the above allegations:

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

138. The following Table illustrates reimbursements and the corresponding harm caused to the States' Medicaid programs as a result of DEFENDANT

PAGES 57 THROUGH 70

HAVE BEEN COMPLETELY REDACTED

WHICH INCLUDES PARAGRAPHS

139 THROUGH 149

[redacted]

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	RELATOR'S WHOLESALER COST	RELATOR'S DIRECT COST
[redacted]		[redacted]		[redacted]	
[redacted]		[redacted]		[redacted]	[redacted]
[redacted]		[redacted]		[redacted]	[redacted]
[redacted]		[redacted]		[redacted]	[redacted]
[redacted]		[redacted]		[redacted]	[redacted]
[redacted]		[redacted]		[redacted]	[redacted]
[redacted]		[redacted]		[redacted]	[redacted]

150. [redacted]

SECTION NO. 12
THE SPECIFIC FALSE PRICE AND COST REPRESENTATIONS OF DEFENDANT DEY AS TO MEDICAID

151. At various times from on or after April 7, 1994, and continuing through the present date, DEFENDANT DEY knowingly caused the States' Medicaid programs to pay false or fraudulent claims for drugs specified in this Section and further made or used false or fraudulent records and/or statements to get such claims paid or approved. As a result of the actions of DEFENDANT DEY and those persons and entities acting directly or indirectly in concert with DEFENDANT DEY, the States' Medicaid programs

paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs specified in this Section. The acts committed by DEFENDANT DEY that caused the States' Medicaid programs to pay or approve said false or fraudulent claims included, but were not necessarily limited to, knowingly making false or fraudulent representations about the wholesaler prices of the drugs specified in this Section which DEFENDANT DEY knew would be used by the States' Medicaid programs in paying or approving claims for the drugs specified in this Section. Each of said representations was in fact used by the States' Medicaid programs in paying or approving claims for the drugs specified in this Section.

152. DEFENDANT DEY knowingly caused its false or fraudulent wholesaler price representations to be transmitted by First Data Bank's automated services made or used false records or statements regarding its wholesaler prices of the drugs specified in this section and submitted them to the States' Medicaid programs continuously throughout the years specified in this section. Within this paragraph is a table, organized by drug and NDC number, which reflects the recent false wholesaler prices in First Data Bank's automated services. The information in the table under the heading "DEY'S Reported False WACs" reflects DEFENDANT DEY'S false representations of price it charged wholesalers for drugs. The heading "Relator's Cost" reflects the true price that DEFENDANT DEY charged the Relator for the drug or caused another entity to charge the Relator for the drug.

DRUG STRENGTH & SIZE, NDC#s	DEY's REPORTED FALSE WACs	RELATOR'S COST (in or about March 2000)
ALBUTEROL INHALATION AEROSOL 17 gm 49502-0303-17	$5.99	$2.90
ALBUTEROL INHALATION AEROSOL (refill) 17 gm 49502-0303-27	$5.74	$2.99

153. The false price and cost representations, as they were submitted to the State of Texas on or after April 7, 1994, are organized in a chart within this paragraph by "Drug", "NDC Number", Texas Medicaid Payment Amount ("WEAC"/"DEAC"), "Relator's Cost", the "Gross Profit" and the percentage of "Gross Profit." The amount under the heading "Relator's Cost" is the true price that DEFENDANT DEY charged the Relator for the drug or caused another entity to charge the Relator for the drug. A comparison of the Relator's cost with DEFENDANT DEY'S price representations shows the falsity of DEFENDANT DEY'S price representations for the specified drugs. Furthermore, the table shows the impact of DEFENDANT DEY'S false statements because it shows health care providers made a profit for prescribing DEFENDANT DEY'S drugs. Texas Medicaid, which intended to pay for drugs based upon estimated acquisition costs, never intended to pay the amounts under the heading "Gross Profit."

DEFENDANT DEY					
Drug	NDC #	WEAC DEAC	Relator's Cost (in or about March 2000)	WEAC Provider's Gross Profit $ DEAC Provider's Gross Profit $	WEAC Provider's Gross Profit % DEAC Provider's Gross Profit %
Albuterol 17 gm	49502-0303-17	$0.39520/gm $6.71 $0.352940/gm $5.99	$2.90	$3.81 $3.09	57% 52%
Albuterol refill	49502-0303-27	$0.378810/gm $6.44 $0.338230/gm $5.75	$2.99	$3.45 $2.76	54% 48%

THE SPECIFIC FALSE PRICE AND COST REPRESENTATIONS OF DEFENDANT DEY AS TO MEDICARE

154. At various times from on or after April 7, 1994, and continuing through the present date, DEFENDANT DEY knowingly caused the Medicare program to pay false or fraudulent claims for drugs specified in this Section and further made or used false or fraudulent records and/or statements to get such claims paid or approved. As a result of the said actions of DEFENDANT DEY and those persons and entities acting directly or indirectly in concert with DEFENDANT DEY, the Medicare program paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs specified in this Section. The acts committed by DEFENDANT DEY that caused the Medicare program to pay or approve said false or fraudulent claims included, but were not necessarily limited to, knowingly making false or fraudulent representations about prices and costs of the drugs specified in this Section which DEFENDANT DEY knew or

should have known would be used by the Medicare program in paying or approving claims for the drugs specified in this Section. Each of said representations was in fact used by the Medicare program in paying or approving claims for the drugs specified in this Section.

155. DEFENDANT DEY knowingly caused its false or fraudulent price and cost representations to be published in the years specified in this Section in the Red Book and further made or used false records or statements regarding its prices and costs of the drugs specified in this Section and submitted same to the Medicare program continuously throughout the years specified in this Section. For the purposes of specificity and particularity, the said false price and cost representations as they were reflected in the Red Book have been organized into a chart form for each drug in question. The information provided under the columns for DEFENDANT's Published Price, and Red Book "AWP" and "DP" reflects the false price and cost representations made by the DEFENDANT DEY. The information under the Relator's Cost columns reflects the true price that DEFENDANT DEY charged the Relator for the drug or caused another entity to charge the Relator for the drug. As a very small pharmacy, the Relator does not always receive the lowest prices available to volume purchasers. Accordingly, a comparison of the Relator's costs with the price and cost representations made by the DEFENDANT DEY establishes the falsity of DEY's representations for the drugs and years specified as follows:

DRUG: IPRATROPIUM BROMIDE
MEDICARE HCPCS J7644 Per mg.

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	RELATOR'S WHOLESALER COST	RELATOR'S DIRECT COST
1999		$44.10		$11.72	$13.50
2000		$44.10		$11.72	$12.00
2001		$44.10		$9.22	$10.00
2002					

156. As a direct and proximate result of the actions of the DEFENDANT DEY, alleged herein, the UNITED STATES has sustained damages recoverable under the False Claims Act, together with treble damages, penalties, attorneys' fees and costs.

[redacted]

157. [redacted]

PAGES 77 THROUGH 172

HAVE BEEN COMPLETELY REDACTED

WHICH INCLUDES PARAGRAPHS

158 THROUGH 208

209. [redacted]

[redacted]

[redacted]

[redacted]

COUNT I

FALSE CLAIMS ACT;
CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS

210. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTs: [redacted]

[redacted], DEY

INC., [redacted]. under the False Claims Act, 31 U.S.C. §§3729-3732.

211. Relator realleges and incorporates by reference paragraphs 1 through 209 as if fully set forth herein and further alleges as follows:

212. The DEFENDANTS from a date on or after April 7, 1994, to the present date, knowingly [as defined in 31 U.S.C., §3729(b)] caused to be presented to officers or employees of Medicare and/or the States' Medicaid programs false or fraudulent claims [as explained in United States v. Neifert-White, 390 US 228, 232-233 (1968)] for payment or approval, in that the DEFENDANTS caused to be presented to officers or employees of Medicare and/or the States' Medicaid programs false or fraudulent price and cost information for the drugs specified herein and caused Medicare and/or States' Medicaid programs to pay out sums of money to the providers and suppliers of the DEFENDANTS' specified drugs grossly in excess of the amounts intended by law, resulting in great financial loss to Medicare and/or the States' Medicaid programs and the UNITED STATES.

213. [redacted]

214. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars ($10,000,000.00), all in violation of 31 U.S.C. §3729(a)(1).

COUNT II

FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

215. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTs: [redacted], DEY INC., [redacted]. under the False Claims Act, 31 U.S.C. §§3729-3732.

216. Relator realleges and incorporates by reference paragraphs 1 through 209 as if fully set forth herein and further alleges as follows:

217. The DEFENDANTS, from a date on or after April 7,1994 to the present date, knowingly [as defined in 31 U.S.C. §3729(b)] caused false records or statements to be made or used to get false or fraudulent claims [as explained in United States v. Neifert-White, 390 US 228, 232-233 (1968)] to be paid or approved by Medicare and/or by the States' Medicaid programs, in that the DEFENDANTS, caused false records or statements of prices and costs of the DEFENDANTS' drugs specified herein to be used by Medicare and/or by the States' Medicaid programs to pay or approve claims presented by the providers and suppliers of the DEFENDANTS' specified drugs, which claims were grossly in excess of the amounts intended by law, resulting in great financial loss to the UNITED STATES.

218. [redacted]

219. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars ($10,000,000.00), all in violation of 31 U.S.C. §3729(a)(2).

COUNT III

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS; ILLEGAL REMUNERATION

220. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTs: [redacted], DEY INC., [redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

221. Relator realleges and incorporates by reference paragraphs 1 through 209 as if fully set forth herein and further alleges as follows:

222. The DEFENDANTS, from on or about April 7, 1994 to the present date, knew that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the DEFENDANTS and upon which the DEFENDANTS knew Medicare and/or Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price

reductions and/or in the form of illegal remuneration from Medicare and/or the States' Medicaid programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which the DEFENDANTS knew that payment would be made, in whole or in part, by Medicare and/or the States' Medicaid programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C§2.

223. The DEFENDANTS knew that Medicare and/or the States' Medicaid programs would not pay or approve claims for the specified drugs if it were disclosed to Medicare and/or to the States' Medicaid programs that said claims were for amounts that included remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

224. The DEFENDANTS also knew that their customers, in presenting claims for the specified drugs to Medicare and/or to the States' Medicaid programs, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

225. The DEFENDANTS' knowing actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2), in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to be false or fraudulent claims and caused the claims to be presented to Medicare and/or to the States' Medicaid programs for payment and approval in violation of 31 U.S.C §3729(a)(1).

226. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (10,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

COUNT IV

FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT; ILLEGAL REMUNERATION

227. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTs: [redacted], DEY INC., [redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

228. Relator realleges and incorporates by reference paragraphs 1 through 209 as if fully set forth herein and further alleges as follows:

229. The DEFENDANTS, from on or after April 7, 1994 to the present date, knew that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the

DEFENDANTS and upon which the DEFENDANTS knew Medicare and/or Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from Medicare and/or from the States' Medicaid programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which the DEFENDANTS knew that payment would be made, in whole or in part, by Medicare and/or the States' Medicaid programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C §2.

230. The DEFENDANTS knew that Medicare and/or the States' Medicaid programs would not pay or approve claims for the specified drugs if it were disclosed to Medicare and/or to the States' Medicaid programs that said claims were for amounts that included remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

231. The DEFENDANTS also knew that their customers, in presenting claims for the specified drugs to Medicare and/or to the States' Medicaid programs, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

232. The DEFENDANTS' knowing actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b)2, in causing the omission of material information from the claims, and in causing the failure to properly disclose

and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to be false records or statements that were made and used to get a false or fraudulent claim paid or approved by the Government. The DEFENDANTS' actions herein caused said false records or statements to be made and used as prohibited by 31 U.S.C. §3729(a)(2).

233. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars ($10,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

COUNT V

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS; PROHIBITED REFERRALS, CLAIMS AND COMPENSATION ARRANGEMENTS

234. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTS: [redacted], DEY INC., [redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

235. Relator realleges and incorporates by reference paragraphs 1 through 209 as if fully set forth herein and further alleges as follows:

236. The DEFENDANTS, from on or after April 7, 1994 to the present date, knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services (outpatient prescription drugs) furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by Medicare and/or the States' Medicaid programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.

237. The DEFENDANTS knew that Medicare and/or the States' Medicaid programs would not pay or approve claims for the outpatient prescription drugs to Medicare and/or the States' Medicaid programs that said claims were for amounts that included claims or bills prohibited by 42 U.S.C. §1395nn(a)(1)(B).

238. The DEFENDANTS knowingly presented or caused their referring physicians, physician groups and outpatient clinics to present claims or bills for the DEFENDANTS' outpatient prescription drugs to Medicare and/or the States' Medicaid programs for payment or approval that were false or fraudulent.

239. The DEFENDANTS' knowing actions in having compensation arrangements for its referring physicians, physician groups and outpatient clinics

prohibited by 42 U.S.C. §1395nn(a)(1)(B) and in presenting or causing the presentment of prohibited claims in violation of 42 U.S.C. §1395nn(a)(1)(B) for payment or approval caused the claims for the outpatient prescription drugs presented to Medicare and/or the States' Medicaid programs to be false or fraudulent claims in violation of 31 U.S.C §3729(a)(1).

240. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars ($10,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

COUNT VI

FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT; PROHIBITED REFERRALS, CLAIMS AND COMPENSATION ARRANGEMENTS

241. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTS: [redacted], DEY INC., [redacted]

[redacted]

[redacted]under the False Claims Act, 31 U.S.C. §§3729-3732.

242. Relator realleges and incorporates by reference paragraphs 1 through 209 as if fully set forth herein and further alleges as follows:

243. The DEFENDANTS, from on or after April 7, 1994, to the present date, knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services (outpatient prescription drugs) furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by Medicare and/or the States' Medicaid programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.

244. The DEFENDANTS knew that Medicare and/or the States' Medicaid programs would not pay or approve claims for the outpatient prescription drugs if it were disclosed to Medicare and/or the States' Medicaid programs that said claims were for amounts that included claims or bills prohibited by 42 U.S.C. §1395nn(a)(1)(B).

245. The DEFENDANTS knowingly made or used or caused their referring physicians, physician groups or outpatient clinics to make or use false records or statements to get false or fraudulent claims and bills for the DEFENDANTS' outpatient

prescription drugs to be paid or approved by Medicare and/or by the States' Medicaid programs.

246. The DEFENDANTS' knowing presentment or causing others to present, claims or bills to Medicare and/or the States' Medicaid programs in violation of 42 U.S.C. §1395nn(a)(1)(B) without disclosing facts revealing said violations constituted the making or using, or the causing others to make or use, false records or statements to get false or fraudulent claims paid or approved in violation of 31 U.S.C. §3729(a)(2).

247. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Million Dollars ($1,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

[redacted]

[redacted]

REQUESTS FOR RELIEF

252. WHEREFORE, the Relator, on behalf of the UNITED STATES, demands that judgment be entered in its favor and against DEFENDANTS: [redacted], DEY INC., [redacted], with judgment to be entered against each DEFENDANT for the amount of damage: to the UNITED STATES arising from claims for each DEFENDANT's respective specified drugs as follows:

253. On Count I (False Claims Act; Causing Presentation of False Claims) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false claim;

254. On Count II (False Claims Act; Causing False Statements To Be Used To Get False Claims Paid By The GOVERNMENT) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS

($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false statement;

255. On Count III (False Claims Act; Causing Presentation of False or Fraudulent Claims; Illegal Remuneration) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false claim;

256. On Count IV (False Claims Act; Causing A False Record Or Statement To Be Made Or Used To Get A False Or Fraudulent Claim Paid Or Approved by the Government; Illegal Remuneration) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false statement;

257. On Count V (False Claims Act; Causing Presentation of False or Fraudulent Claims; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false statement;

258. On Count VI (False Claims Act; Causing a False Record or Statement to be Made or Used to get a False or Fraudulent Claim Paid or Approved by the Government; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN

THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false statement;

[redacted]

260. For all fees and costs of this civil action; and

261. For such other and further relief as the Court deems just and equitable.

Further, the Relator, on its behalf, requests that it receive the maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Relator requests that its award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

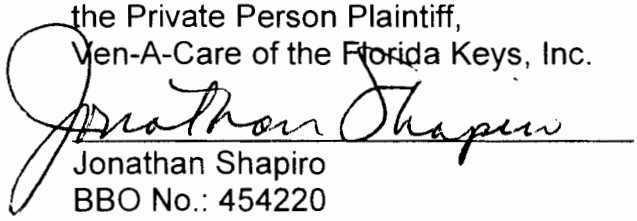
CIVIL ACTION NO. 00 CV 10698 MEL

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Dated: February 1, 2002

Respectfully submitted,
Attorneys for
the Private Person Plaintiff,
Ven-A-Care of the Florida Keys, Inc.



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CIVIL ACTION NO. 00 CV 10698 MEL

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of February, 2002, I caused an original and a copy of this Second Amended Complaint to be filed under seal and in camera for sixty (60) days and not to be served on the DEFENDANTs named herein or until further order of this Honorable Court.

I HEREBY CERTIFY that prior to this 1st day of February, 2002, I caused a copy of this Second Amended Complaint and written disclosure of substantially all material evidence and information the Relator, VEN-A-CARE possesses to be served on the Government pursuant to Rule 4(i)(1)(A) and (B), Fed.R.Civ.P., prior to the filing of this Second Amended Complaint by delivering a copy of the Second Amended Complaint, material evidence and information to the United States Attorney for the District of Massachusetts, and by sending a copy of the Second Amended Complaint, material evidence and information by Certified Mail, Return Receipt Requested, to the Attorney General of the United States in Washington, D.C.

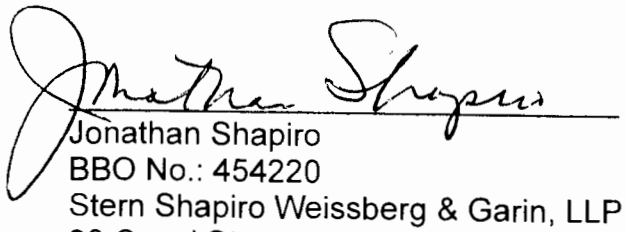

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EXHIBIT 1

TO: WBB

AT: 13055778545

TEXAS DEPARTMENT OF HEALTH

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
(512) 458-7111

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Under the Omnibus Budget Reconciliation Act (OBRA) of 1990, the state of Texas Vendor Drug Program will continue to request completed questionnaire as a requirement for the production addition to the Texas Vendor Drug Index (TVDI). A form is included so that all necessary information from the manufacturer will be available for pricing and dosing recommendations. Questionnaires should be limited to no more than 20 per submittal request for any one month period. A separate questionnaire is to be submitted for each drug and strength. Please supply a cover sheet listing all products, strengths and package sizes for which you are submitting applications. Questions must be answered in full (NO - N/A). This form may be reproduced.

All inquiries regarding this questionnaire for BVD and revisions are to be directed to:

Texas Department of Health
BureauVendor Drug
1100 West 49th Street.
Austin, Texas 78756-3174

Drugs are listed in the BVD using the NDC number of the manufacturer or distributor who is holding the drug forth as his own and has his company's name on the label of the container that is sold to the pharmacy. If your company has a product to which the "New Drug Coverage" applies, please add the FDA approval date of the New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug Approval (ADA) to the questionnaire.

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug
(512)338-6965
(512)338-6462-Fax
(512)338-6932-Secretary

EXHIBIT "1"

REQUEST FOR INFORMATION FOR NEW DRUG PRODUCT OR FOR ADDITIONAL INFORMATION OF PRODUCTS CURRENTLY INCLUDED IN TEXAS MEDICAID

Please fill out the following information for consideration on Texas Medicaid

CLUDE A COPY OF FILE CARD, PACKAGE INSERT AND OR MATERIAL FOR PHYSICIANS

DRUG DESCRIPTION		
DC. NO: ıultiple package size of same strength	PACKAGE QTY: products may be included\	
RODUCT BRAND NAME: ENERIC NAME: *STRUCTURALLY RELATED DRUGS:		
.RUG STRENGTH:		
OLOR:	FLAVOR:	ORANGE BOOK RATING:
OSAGE FORM:	IS THIS DRUG LEGEND OR OTC?	DEA SCHEDULE OF THE DRUG:
IAXIMUM DAILY DOSE:		
ECOMMENDED DAILY DOSE:		
NGREDIENTS/DESCRIPTION:		
*LIST SHELF LIFE:		
*ESTIMATED AVG. DURATION OF THERAPY:		
*MAXIMUM DURATION OF TREATMENT:		

A - Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products.

B - Drug products that FDA at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

C - Not listed in Orange Book

** NEW ADDITIONAL INFORMATION - revised (April 1, 1998)

ATTACH COPIES OF PRICE LIST & ADD TO MAILING LIST IF NOT CURRENTLY LISTED**

PRICE INFORMATION

AVERAGE OF SUGGESTED WHOLESALE PRICE TO PHARMACY (AWP)	$
PRICE TO WHOLESALER AND/OR DISTRIBUTOR	$
DIRECT PRICE TO PHARMACY	$
PRICE TO CHAIN WAREHOUSE	$
INSTITUTIONAL OR OTHER CONTRACT PRICE** (Nursing Home, Home Health Care)	$
OTHER PRICE	$

One set of price lists is sufficient for multiple submittals.

Notes: If prices vary by specific contract or customer arrangement, you may provide a price range.**

Please circle the companies to whom you report pricing information.

FIRST DATA BANK PRICE ALERT RED BOOK

MEDI-SPAN BLUE BOOK

OTHER:_____

Do you sell to distributors, repackagers, or relablers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number?

If yes, attach a listing.

Attach a copy of your sales agreement with retail pharmacists (contract, policy, etc)

Attach a copy of your Vendor Liability Insurance:

a. Included or

b. Previously submitted or unchanged. (Do not need to resubmit)

Available date through WHOLESALERS_____

ame of firm:		
ddress:		
ity:	State:	Zip:
ame and address of Manufacturer of drug:		
ity:	State:	Zip:
ame and Address of representatives/government affairs persons covering the Texas area; if applicable:		
ity:	State:	Zip:
hone:		

Is this product now marketed under an approved NDA or ANDA?

Submit a copy of the FDA letter of approval of the NDA or ANDA, or, if not applicable, a copy of the FDA letter of approval for marketing.

Please circle DESI classification of this product.

2 Non-DESI/IRS: safe and effective

3 DESI/IRS under review

4 LTE DESI/IRS for some indications

5 Non-Covered - LTE DESI/IRS for all indications

6 Non-Covered - LTE DESI/IRS withdrawn form the market

oduct added to the Texas Vendor Drug Program must bear the labeler code, as defined by the FDA, of the ty, with the exception of a bonafide full-service drug wholesaler, marketing the final sale to the provider.

nufacturers or distributors having one or more of their pharmaceuticals included in the program are responsible submitting notification of any changes pertaining to any of the above information not later than such revisions scheduled to occur to:

Texas Department of Health
Bureau of Vendor Drug
Attn: Martha McNeill, R.Ph.
Director of Product Management
1100 West 49th Street
Austin, Texas 78756-3174

tify that the information submitted is correct to the best of my knowledge and that this product is not now in lation of either Federal or State Law. I also agree to inform the Texas Department of Health, in writing, of any nges in formulation, product status, price or availability as herein describe, within fifteen (15) days of such nge.

sponsible Person (Type or Print) _____ Signature _____

_____

dress _____ City _____ State _____ Zip _____

mpany Name _____ ( ) Telephone _____

EXHIBIT 2

Point-of-Care Knowledge Bases
First DataBank

New Product Submission Form

For your convenience, you may use this form to add products to the National Drug Data File (NDDF). Please make copies of this form for each add.

NDC Number	
UPC Number	
Product Name	
RX or OTC	
Package Size (ml, gm, each)	
Dosage Form (tablet, capsule, powder filled vial, ampul, ointment, etc..)	
Wholesale (Distributor) Price	
Direct Price	
AWP Price	
Effective Date (start ship date)	
Active Ingredients & strengths (Package Insert and Label are preferred.)	

Company Name: _____
Your Name: _____
Telephone: _____

The Hearst Corporation, 1111 Bayhill Drive, San Bruno, California 94066 Tel: (415)588-5454 Fax: (425)588-6867

EXHIBIT "2"

EXHIBIT "3" THROUGH EXHIBIT "6"

HAVE BEEN COMPLETELY REDACTED